

REMARKS

Status of the claims

Claims 1-9, 11, 13 and 15-24 are pending in the application. Claims 1-9, 11, 13 and 15-24 stand rejected. Claim 21 has been canceled. Claim 22 is amended. No new matter has been added.

Claim objections

Claim 21 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Claim 21 has been canceled. Claim 22 has been amended to depend on claim 1. Claims 23 and 24 correctly depend on claims 22 and 23 respectively. In view of these changes, the Applicants respectfully request that the objection to claim 21 under 37 CFR 1.75(c) be removed.

Double patenting

Claim 21 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 1.

Claim 21 has been canceled. In view of this change, the Applicants respectfully request that the objection to claim 21 under 37 CFR 1.75 be removed.

The 35 U.S.C. §103 rejection

Claims 1-9, 13 and 15-22 are rejected under 35 U.S.C. §103(a) as being unpatentable over **Gordon** (U.S. Patent No. 4,889,120) in view of **Sawyer**

(U.S. Patent No. 5,824,015) in further view of **Hegde et al.** (U.S. Patent No. 6,656,174). The Applicants respectfully traverse this rejection.

In rejecting independent claim 1, the Examiner states that **Gordon** discloses a method of treatment for tissue substrates in an individual comprising the steps of securing a tissue substrate proximal to a ferromagnetic metal susceptor, applying radiofrequency energy that generates a magnetic field to the substrate or susceptor to generate heat, and affixing the substrate together with the heat. The Examiner concedes that **Gordon** fails to explicitly recite controlling the affixing of the substrates via feedback monitoring of a property of the substrate, the energy or a combination thereof, wherein the property is heat, an electrical property, eddy currents, conductivity, or frequency changes or a combination thereof.

The Examiner asserts that it is well known in the art that the connection of different portions of biological tissue can be effected by crosslinking of collagen and heated by various means. The Examiner also states that **Sawyer** discloses a method for welding biological tissue and teaches temperature range of 45°C to 75°C in order to form tissue welds/seals. The Examiner further states that **Hegde et al.** disclose device featuring interior temperature sensors and method for heating treating biological tissue with RF energy.

The Examiner concludes that it would have been obvious to a person of ordinary skill in the art to modify the invention of **Gordon** as taught by **Sawyer** to provide heating temperature range for the treated tissue site in order to achieve collagen crosslinked tissue seal/weld and as further taught by **Hegde et al.**, to

provide the system with temperature sensor and temperature-feedback control in order to obtain and maintain a particular tissue treatment site temperature. The Applicants respectfully disagree.

Applicants submit that **Gordon** discloses a method of creating connections between biological structures by applying electromagnetic energy to generate heat and altering intracellular particles within the edges of biological structures as well as the edges of biological structures with the purpose to connect the biological structures. **Gordon** describes the use of artificially introduced particles which react with an applied electromagnetic field to generate heat to connect the biological structures.

Applicants submit that **Sawyer** discloses a method of joining cylindrical biological structures, comprising drawing ends of the cylindrical biological structures together, placing weldable material over the ends and applying energy to the weldable material while the ends of the cylindrical biological structures remain drawn together, denaturing or melting the weldable material and adjacent biological structures with the applied energy to cause mixing of the denatured or melted weldable material and adjacent biological tissue, thus joining or restructuring the biological structures. **Sawyer** also mentions temperature ranges suitable to denature certain proteins.

Applicants submit that **Hegde et al.** teach a device and method for creating circumferential lesions in and around veins, coronary vessels and other parts of the body without obstructing blood flow. In one particular embodiment, **Hegde et al.** disclose a catheter device which comprise interior electrodes and

temperature sensing elements that are electrically coupled to an RF generator and controller, allowing RF power to be delivered to the targeted tissue under temperature-feedback control. Furthermore, **Hedge et al.** specifically teach that the temperature of the tissue is measured.

The Applicants respectfully submit that the cited prior art references do not render the claimed invention obvious because there is no motivation to combine **Gordon, Sawyer** and **Hedge et al.** First of all, while **Gordon** and **Sawyer** both teach a method for fusing biological structures, **Hedge et al.** teach a method for ablating or creating lesions in biological structures. Therefore, a person of ordinary skill in the art would have no motivation to combine **Hedge et al.** with **Gordon** and/or **Sawyer** because the goals of the disclosed methods are mutually exclusive.

Secondly, the temperature sensor and control recited in **Hedge et al.** is used to create lesions and ablations. This is also incompatible with what **Gordon** and **Sawyer** seeks to accomplish, i.e., to fuse biological structures. The recited steps in the claimed invention "affixing said substrate(s) via said heat thereby effecting treatment; and controlling the affixing of said substrate(s) via feedback monitoring of a property of said susceptor, said energy or a combination thereof" is clearly antithetical to the teachings of **Hedge et al.** which seeks to ablate substrate via temperature sensing and monitoring. A person of common sense would not combine a step which controls the degree of ablation of a substrate (**Hedge et al.**) with steps involving the fusion of the same substrate (**Gordon** and **Sawyer**).

Thirdly, the temperature feedback element of the claimed invention measures the temperature of the susceptor and/or energy: "controlling the affixing of said substrate(s) via feedback monitoring of a property of said susceptor, said energy or a combination thereof" (instant claim 1). In distinct contrast, the temperature feedback recited in **Hedge et al.** is restricted to sensing the temperature of the tissue (col 9, line 10). **Hedge et al.** does not teach or suggest that temperature feedback may be controlled via measurement of the susceptor or the RF energy as recited in the claimed invention. This deficiency of **Hedge et al.** is not remedied by **Gordon** and/or **Sawyer** as neither suggests temperature feedback control via sensing the susceptor and/or RF energy.

Lastly, MPEP 2143.01 states that the proposed modification of combining references "cannot render the prior art unsatisfactory for its intended purpose." The Applicants respectfully submit that for the reasons mentioned above, namely that **Hedge et al.** teaches temperature feedback control in order to ablate tissue, the combined references **Gordon**, **Sawyer** and **Hedge et al.** would render the claimed invention inoperable for its intended purpose.

In view of the arguments presented herein, the Applicants submit that claims 1-9, 13 and 15-22 are not obvious under 35 U.S.C. §103(a) over **Gordon** (U.S. Patent No. 4,889,120) in view of **Sawyer** (U.S. Patent No. 5,824,015) in further view of **Hedge et al.** (U.S. Patent No. 6,656,174). Accordingly, Applicants respectfully request that the rejection of claims 1-9, 13 and 15-22 under 35 U.S.C. §103 be removed.

Claim 11 is rejected under 35 U.S.C. §103(a) as being unpatentable over **Gordon** (U.S. Patent No. 4,889,120) in view of **Sawyer** (U.S. Patent No. 5,824,015) in further view of **Hegde et al.** (U.S. Patent No. 6,656,174) as applied to claim 1 above, and in view of **Aida et al.** (U.S. Patent No. 5,897,495). The Applicants respectfully traverse this rejection.

In rejecting claim 11, the Examiner states that **Gordon** in view of **Sawyer** and further in view of **Hedge et al.** disclose the claimed invention except for explicitly reciting the radio frequency energy being applied in pulses. The Examiner contends that it is well known in the art that radiofrequency may be applied in a continuous duration or in discreet pulses. The Examiner further states that **Aida et al.** disclose a system and method of heat-treating tissue and teach a transmitter coil for transmitting RF pulses. Thus, the Examiner concludes that it would have been obvious to one of ordinary skill in the art to modify the invention of **Gordon** in view of **Sawyer** and further in view of **Hedge et al.**, as taught by **Aida et al.**, to provide RF energy in pulses in order to heat-treat tissue. The Applicants respectfully disagree.

As discussed *supra*, the combination of **Gordon**, **Sawyer** and **Hegde et al.** does not render independent claim 1 obvious. This deficiency is not overcome by **Aida et al.** which is not applied to teach temperature sensing and control for the purpose of fusing substrates or sensing the susceptor and/or energy, as recited in the instant claims. Dependent claim 11 which further limits claim 1 is also nonobvious.

In view of the arguments presented herein, the Applicants respectfully request that the rejection of claim 11 under 35 U.S.C. §103 be removed.

Claims 23 and 24 are rejected under 35 U.S.C. §103(a) as being unpatentable over **Gordon** (U.S. Patent No. 4,889,120) in view of **Sawyer** (U.S. Patent No. 5,824,015) and in further view of **Hegde et al.** (U.S. Patent No. 6,656,174) in still further view of **Eggers et al.** (U.S. Patent No. 5,366,443). The Applicants respectfully traverse this rejection.

In rejecting claims 23 and 24, the Examiner states that **Gordon** in view of **Sawyer** in further view of **Hegde et al.** disclose the claimed invention except for heat is monitored via infrared optical detection. The Examiner asserts that it is well known in the art to provide temperature sensors in various alternate/equivalent means such as thermistors and infrared optical sensors for example. The Examiner also states that **Eggers et al.** disclose a medical device and method and teach temperature sensing using infrared sensing. Thus the Examiner concludes that it would have been obvious to one of ordinary skill in the art to modify the invention of **Gordon** in view of **Sawyer** in further view of **Hegde et al.**, as taught by **Eggers et al.** to provide the device and system with fiber optics with infrared sensing.

As discussed *supra*, the combination of **Gordon**, **Sawyer** and **Hegde et al.** does not render independent claim 1 obvious. This deficiency is not overcome by **Eggers et al.** which is not applied to teach temperature sensing and control for the purpose of fusing substrates or sensing the susceptor and/or energy,

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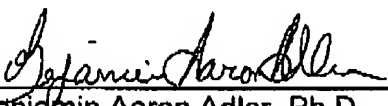
as recited in the instant claims. Dependent claims 23 and 24 which further limits claim 1 are also nonobvious.

In view of the arguments presented herein, the Applicants respectfully request that the rejection of claims 23 and 24 under 35 U.S.C. §103 be removed. The Applicants believe that all pending claims are now in condition for allowance.

This is intended to be a complete response to the Final Office Action, mailed October 22, 2009. If any issues remain outstanding, the Examiner is respectfully requested to telephone the undersigned attorney of record for immediate resolution. Applicants enclose a Petition for One Month Extension of Time. Please charge the \$65 extension fee under 37 C.F.R. §1.17(a) to the credit card identified on the enclosed Form PTO-2038. Only in the absence of Form PTO-2038, please debit any applicable fees from Deposit Account No. 07-1185, upon which the undersigned is allowed to draw.

Respectfully submitted,

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